

REMARKS

The Official Action of June 3, 2004, and the prior art relied upon therein have been carefully reviewed. The claims in the application are now claims 8, 42 and 43, and these claims define patentable subject matter under Sections 102, 103 and 112, and consequently should be allowed. Accordingly, the applicants hereby respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

As regards the restriction and election requirements, applicants have now deleted without prejudice all of the non-elected subject matter. Such deletion is of course made with applicants reserving their rights, including those rights provided by Sections 121, 120 and 119, to pursue the non-elected subject matter in a divisional application.

Claims 40 and 42-45 have been objected to on the basis of an informality in claim dependency. Such informality and the objection are obviated by the amendments presented above.

Claims 8-13, 40 and 42-45 have been rejected under the second paragraph of Section 112. This rejection is respectfully traversed.

A number of the so-rejected claims have been deleted without prejudice to applicants' rights to pursue such subject matter in a continuing application if applicants choose to do so, such rights including those rights provided by Sections 120 and 119. As regards such subject matter in the now cancelled claims, no further reply is necessary at the present time.

As regards the claims remaining, namely claims 8, 42 and 43, all essential matter is claimed (although applicants do not concede that the claims as previously recited did not contain all essential matter).

Thus, Claim 8 as amended defines the claimed composition for gene therapy, used for treating a disease susceptible to gene therapy, as containing as active ingredients (1) an effective amount of a retrovirus that contains a gene useful for gene therapy; (2) an effective amount of a functional substance having heparin-II-binding domain of fibronectin; and (3) an effective amount of vascular endothelial cells. The amendments are supported by the description of Examples 4 and 5.

Applicants respectfully request withdrawal of the rejection.

Claims 8-13, 40 and 42-45 have been rejected under the first paragraph of Section 112 as allegedly failing to meet the description requirement. This rejection is respectfully traversed.

Again, applicants need not reply at the present time to this rejection insofar as the previously pending and now cancelled claims are concerned, in view of the amendments presented above. Again, for the record, applicants reserve the right to pursue the cancelled subject matter in a continuing application if applicants choose to do so, applicants in such a case relying on their rights provided by law, including those of Sections 120 and 119.

As regards claims 8, 42 and 43, applicants submit that there should be no doubt regarding full compliance with the written description requirement. Those skilled in the present art are highly skilled, and there is no doubt that applicants' specification reasonably conveys to those highly skilled persons that the present applicants had possession of the claimed invention at the time the present invention was made.

As noted above, applicants' claims are fully supported by the description set forth in Examples 4 and 5 of the present specification.

Applicants respectfully request withdrawal of the rejection.

Claims 8-13, 40 and 42-45 have also been rejected under the first paragraph of Section 112 because of an alleged lack of enablement. This rejection also is respectfully traversed.

Again, as already stated above, the amendments submitted above are not to be taken as any abandonment by applicants of the previously claimed subject matter, as applicants hereby reserve their rights to pursue such subject matter in a continuing application. However, at the present time, applicants need not address the rejection insofar as the previously pending and now cancelled claims are concerned.

As regards the presently pending claims 8, 42 and 43, they are fully enabled, applicants again noting the full enabling disclosure of Examples 4 and 5, and the fact that those skilled in the present are highly skilled persons. Even if some experimentation were necessary, not conceded, such experimentation would only be routine, and that is fully permissible. The PTO has no basis for disbelieving what is set forth in applicants' specification.

Applicants respectfully request withdrawal of this rejection.

Claims 8-11, 40 and 42-45 have also been rejected under Section 102 as anticipated by Jolley et al WO '566 ("Jolley"), and claims 8-13, 40 and 42-45 have been similarly rejected under Section 102 as anticipated by Williams WO '604 ("Williams"). These rejections are respectfully traversed.

Again, for the record, applicants need not address these rejections insofar as they were applied by the PTO against subject matter which is not presently being claimed. On the other hand, applicants expressly do not abandon such subject matter, but instead reserve their rights to pursue such subject matter in a continuing application. Applicants also note for the record that the two citations have not been applied under Section 103, i.e. there is no issue of the existence of any obviousness.

Applicants' claimed invention, as per claims 8, 42 and 43, clearly constitutes novel subject matter over both Jolley and Williams. Thus, as indicated above, claim 8 calls for a composition containing three active ingredients, namely a retrovirus containing a gene useful for gene therapy, a functional component having heparin-II-binding domain of fibronectin, and vascular endothelial cells.

According to the disclosure of Jolley, a gene delivery vehicle is targeted to a cell using a targeting element capable of binding to the cell (see, for example, claim 1 of Jolley). Although antibodies and the like are disclosed in Jolley as examples of the targeting elements (see, for example, page 8, line 16 to page 9, line 32 of Jolley), this citation contain no disclosure concerning the use of a cell such as a vascular endothelial cell as a functional substance having an affinity for a target cell in the claimed composition. Thus, the claimed invention is different from and novel over the subject matter contained in Jolley.

According to the rejection, Williams teaches a composition that comprises a retrovirus vector, heparin-II-binding domain of fibronectin, and a hematopoietic stem cell. As described above, the claimed composition contains vascular endothelial cells. Because a vascular endothelial cell is quite different from a hematopoietic stem cell, and because Williams contains no disclosure concerning the use of a vascular endothelial cell as a functional substance having an affinity for a target cell, the claimed invention is different from and novel over the subject matter contained in Williams.

In conclusion, the claimed invention is not anticipated by Jolley or Williams. In addition, since the

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cited references contain no disclosure concerning the use of vascular endothelial cells, the claimed invention would not have been obvious from either citation or even if the cited references were combined.

Withdrawal of the rejections based on Section 102 is respectfully requested.

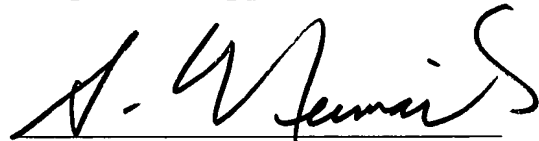
The prior art documents of record and not relied upon have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently pertinent to warrant their application against any of applicants' claims.

Applicants respectfully request favorable reconsideration and allowance.

Respectfully submitted,

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